

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P200201661 WO | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/DK 03/00809 | International filing date (<i>day/month/year</i>) 26.11.2003 | Priority date (<i>day/month/year</i>) 26.11.2002 |
| International Patent Classification (IPC) or both national classification and IPC A61M39/10 | | |
| Applicant UNOMEDICAL AS et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the opinion

II ☐ Priority

III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

IV ☐ Lack of unity of invention

V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand 07.06.2004 | Date of completion of this report 25.01.2005 |
| Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div> | Authorized Officer Krantz, L Telephone No. +49 89 2399-2523 |



**INTERNATIONAL PRELIMINARY
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International application No. PCT/DK 03/00809

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

2-5, 9-11 as originally filed
 1, 6, 7, 8 received on 23.10.2004 with letter of 21.10.2004

Claims, Numbers

1-13 received on 23.10.2004 with letter of 21.10.2004

Drawings, Sheets

1/8, 3/8-8/8 as originally filed
 2/8 received on 23.10.2004 with letter of 21.10.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 13

because:

☒ the said international application, or the said claims Nos. 13 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-12 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-12 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-12 |
| | No: Claims | 13 |

2. Citations and explanations

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see separate sheet

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claims 1 and 13 are independent
claim 13 is for a method.

The following document cited in the International Search report
will be referred to by means of the following appellation
(the document has already been mentioned in a prior communication):
D1 : WO-A-99-36009

III

Claim 13 concerns therapy PCT-Rule 67.1.iv
A urine discharge bag 34 , 37 fig 8 is used in a therapy.
Any action in connection with such a bag when used on a patient
is a step in this therapy.
If the Applicant enters a european application phase claim 13 should be
deleted due to Article 52.4 EPC.

V

The subject-matter of claim 1 is considered new and inventive
within the MEDICAL field:
No available prior art within the medical field discloses
a two-part connector for two tubings having:
- sealing elements on each part which also act as a locking device

- separator elements which become active by relative rotation of
the two parts AND simultaneously exert an axial force to open
the locking device AND is in an axial distance from the locking device.

The documents from the search reports show the following features:

US-A-4 306 705 shows only horizontally-sliding open-close mechanisms
7 fig 2 for tubing connectors.

D1 : WO-A-99-36009 figures 2 and 3 : edges or shoulders 32 and 50

abut in an assembled state but they have no separating function.
Between edges 14 and 42 there is no axial force by relative rotation ,
since they are both "vertical".

Page 17 and fig 7 : There are no axial forces between
abutting ring 103 and end surface 115.

US-A-4 895 570 In fig 3 all movements are sliding left-right and only
in figs 5 and 6 is there turning movements due to helical thread 71 - 73.
In figs 5 and 6 a turning of locking ring 28 will provide an axial force
due to thread 71 - 73.

Yet this will only move ring 28 towards the right (from fig 6 to fig 5)
and open the splayed segments 26 so they do no more grip flange 14 ,
the sealing between port 30 , 32 and pin 20 , 22 is between
tubular projection 36 and pin 20 and this sealing will not disappear
just because ring 28 is turned. Thus to open sealing 20 , 36 a pulling is
necessary IN ADDITION to turning ring 28.

WO-A-93-3787 In fig 4 the only sealing elements which can be identified
BETWEEN tubes 18 (bottom) and 48 (top) is seal 36 penetrated
by needle 44. Yet this seal 36 , 44 provides no locking function
but will detach easily when threads 69 a + b are unscrewed. It is also doubtful
if the cylindrical surface 44 of a needle can be called a "sealing element".
A thread 69 a + b is normally considered to be sufficient attachment
between two parts whereby it is not obvious to provide the cap 50 and
port 27 structure in fig 4 with any FURTHER locking means .

EP-A-633 039 in fig 3 the O-ring 6 is squeezed against conus 4
but forms no locking , that securely can hold male-part 3 and female-part 2
together. The only locking is done by taps 7 (Bajonett-Zapfen 7)
being behind protrusion 11 fig 4 (Rastnocken 11).

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Original disclosure of claim 1 , PCT-Article 34.2.b

claim 1 corresponds original claim 1 with the following exceptions:

- it has been indicated in the first line that the connector is for medical use
- minor grammatical errors have been corrected eg. line 1:
original claim 1 "for at tubing"
now "for a tubing"
original line 15 "configured for and by moving"
now "and" has been deleted , the word was superfluous.

V .3

Division of claim 1 in two portions is not correct PCT-Rule 6.3.b
In an earlier communication the Applicant was asked to indicate
according to which prior art claim 1 is divided in two portions in line 11.
The Applicant has not given this information and actually claim 1
should be divided further down in line 22 according to prior art D1
for the following reasons:

The two parts in D1 fig 2 (male part) and fig 3 (female part)
are used in the medical urologic field and are pushed together
to form a tubular connection see D1 page 12 line 27 "tight fit" .
A tubing 40 (see fig 1) is mounted on the cylindrical portion 46 fig 3.

Therefore 46 may well be called a "first connecting element 46"
for a tubing element 40 and the second member 48 , 50 , 51
in D1 fig 3 may well be called a "first unit" to match the terminology
used in claim 1 of the invention .

Thus fig 3 in D1 shows a "first unit" 50 , 51 with
a "tubular female part" 41 , 42 and a "first connecting element " 46
for a tubing element 40.

The first member 10 in D1 fig 2 may well be called a "second unit"
having a tubular male part
(fits into tapered portion 48 fig 3)
and a collar 36 and second sealing elements 16 (locking recess 16).
In claim 1 of the invention the FUNCTION of the separator elements
is not yet specified in line 9 , not until line 25 is
an axial separating force mentioned.

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Since the step 42 in D1 fig 3 by assembly abuts second end 14 fig 2 these faces 14 and 42 may well be called separator elements since they contribute to prevent that the male (fig 2) and female (fig 3) parts are pushed further together.

Therefore D1 figures 2 and 3 disclose all features of claim 1 until line 22 which should have been formulated :

"by means of the locking device characterised in that said faces being such arranged"

The features in claim 1 until line 22 are seen as follows in D1 figs 2 and 3:

- first unit 50 , 51 connecting element for tubing 40
- first connecting element 46 for tubing 40
- second tubular female connecting element 42 , 48
- first sealing element 44 (ridge 44 for recess 16)
- second unit 10 , 14 (tubular male) with a collar 36
- second sealing element 16
- separator elements 11 - 42 or 36 - 50
- locking device : when recess 16 holds ridge 44
- the separator elements 14 , 42 comprise faces 14 and 42 being in abutment against each other when the two units fig 2 and fig 3 are kept together by locking 16 , 44.

This abutment is because lengths 30 and 39 are equal
see D1 page 12 line 29:

"... the length of the first surface 39 is approximately equal to ... 30"
Yet these two faces 14 and 42 create no axial force by turning as in claim 1 line 25 of the invention .

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Other problems

The drawings especially fig 7 do not meet the requirements of
PCT-Rule 11.13.a , c and m.

Thus fig 7 is a dim copy of a photo where only the contours are visible.

Fig 7 is unsuited for photographic reproduction to size two-thirds.

The other figures appear to be copies of sketches in brochures.

✱

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A connecting piece for a tubing

The invention relates to a connecting piece for a medical tubing, such as a tubing for connecting a catheter with a urine bag, the connecting piece comprising a first unit and a second unit, said first unit comprising a first connecting element for a tubing element and a second connecting element for the second unit, said second connecting element comprising a tubular female part for engagement with the second unit, and first sealing elements, and said second unit comprising a tubular male part with a collar; and second sealing elements for cooperating with the first sealing elements; said first and second units further comprising separator elements.

DE-U-29818311 teaches a connecting piece in particular for medical infusion systems. That connecting piece comprises a male and a female part, wherein the male part is further provided with a collar with undercuts, said undercuts fitting into a corresponding collar on the female part such that the two undercuts combine to form a kind of hook connection, whereby the male and the female parts are securely locked by means of those devices when the connecting piece is assembled. However, it is associated with the drawback that said locking elements that also serve more or less as separator elements are arranged externally on the connecting piece, with an ensuing increased risk of breaking off or becoming damaged during mounting or dismounting. Likewise, it is a matter of concern that when used repeatedly the hooks will come to suffer from material fatigue and break due to the forces to which they are exposed, in particular during dismounting. The minute these locking elements break off, the connecting piece is very likely to leak, due to the sealing as such being accomplished exclusively by a press-fitting between the inner face of the female part and the outer faces of the male part.

Moreover, the system is associated with the drawback that when the male and the female part are to be separated it is possible to perform this only the

means is displaced to its position such that free liquid passage is allowed. The optionally filled bag, preferably a urine bag, being in connection with the female part can flow be emptied into the collector receptacle.

- 5 The invention will now be explained in further detail with reference to the drawing, wherein

Figure 1 is an exemplary embodiment of a connecting bag according to the invention and seen in a perspective view;

10

Figure 2 shows the disclosures of Figure 1, shown cut through in the central plane;

Figure 3 is a sectional view of the section encircled in Figure 2;

15

Figures 4, 5, 6 show different situations for the mutual arrangement of the male and the female parts during their assembly,

20

Figure 7 shows the male and the female parts, separate and in perspective view;

Figure 8 shows the connecting piece for use in connection with a urine leg bag and a collector bag.

25

Figures 1 and 2 show a connecting piece 1 comprising a first unit 3 and a second unit 4, wherein the first unit 3 constitutes the so-called female part. The first unit 3 comprises a first connecting part 5 configured as a stub and for being connected to a tubing 2 in the form of a tubing element 6 that is connected primarily to a urine bag or constitutes a catheter tubing. Opposite

30

the tube stub the second connecting part 7 is arranged, which is also hollow

and cylindrically tubular such that liquid is enabled to pass from the first connecting part 5 to the second connecting part 7.

Typically, between the first and the second connecting part a valve 30 is introduced, said valve 30 being in its inner cavity provided with a displacer means 31 that has an opening and a closing position. In the opening position liquid may penetrate through a bore opening in the displacer means, the outer face of the displacer means being congruent with the inner faces of the valve housing, while, in its closing position, it will perform a closing of the liquid passage that exists between the first and the second connecting part.

Moreover, at each end the displacer means is provided with so-called stops 32, ie annularly extending beads having a larger diameter than the displacer means and the interior diameter of the housing as such, whereby it is prevented that the displaceable displacer means 31 is offset entirely out of the housing during use thereof.

The second connecting part 7, which is thus a female part, encloses the second unit 4 of the connecting piece 1, which is, in principle, a male part, and comprising a tubular male part section 10.

The second unit will, opposite the other end, be provided with a stub 35 into which a tubing can be shifted, whereby further liquid passage through the entire connecting piece 1 is enabled through this tubing 2. As mentioned, the second unit 4 comprises this male part, whose outer face is essentially congruent with the inner face of the female part and is delimited by a collar 11, said collar 11 having a delimiting 15 which follows the shape of a wave such that undercuts are not formed.

This means that the delimiting edge 15 of the collar is a continuously extending delimiting edge in such a manner that a connecting line between

any two points in relation to the horizontal plane does not exceed 90°. Typically the collar will comprise two tongues 16, and wherein these tongues are arranged diametrically opposite each other.

5 The delimiting edge 17 of the female part will have a course that is congruent with the delimiting edge 15 of the collar and having an outer diameter that corresponds to the outer diameter of the collar to the effect that there is an even transition from the first unit 3 to the second unit 4. During twisting, ie
10 dismounting of the second unit 4 from the first unit 3, they are turned in mutually opposite directions, whereby forces are transmitted in the edge area between the delimiting edges of the female and male parts, and due to the inclined course, a turning off will occur, whereby the rotating movement is translated into an axially extending force component, whereby the male part is shifted out of the enclosure of the female part.

15 However, the delimiting edge 15 of the collar may assume several shapes other than the waved shape; it may be eg triangular flaps/tongues, and likewise there may be more than two. It is essential, however, that there are no less than two, precisely to ensure that the male part is not twisted wrongly
20 during dismounting.

Figure 7 shows the waved course of the collar for providing two tongues and the corresponding congruent course of the female part for also providing two tongues.

25 The area between the delimiting edges of the male and the female part thus constitutes the separator elements 13 of the connecting piece 1. Opposite this area, inasmuch as the tubular part 8 of the female part is concerned, the sealing elements 9, 12 as such are arranged as is the locking device 14 that
30 will be subject to further discussion with reference to Figures 3-6.

Patent Claims:

1. A connecting piece (1) for a medical tubing (2), such as a tubing for connecting a catheter with a urine bag, said connecting piece comprising a first unit (3) and a second unit (4), said first unit (3) comprising a first connecting element (5) for a tubing element (6) and a second connecting element (7) for the second unit (4), said second connecting element comprising a tubular female part (8) for engagement with the second unit (4) and first sealing elements (9), and said second unit (4) comprising a tubular male part (10) with a collar (11) and second sealing elements (12) for cooperating with the first sealing elements (9), said first unit (3) and second unit (4) comprising respective separator elements (13), **characterized in**

that the first sealing elements (9) and the second sealing elements (12) are configured for being mutually engageable by moving the male part (10) and the female part (8) axially towards each other for establishing a locking device (14), by which the first unit (3) and the second unit (4) are kept together;

that the separator elements (13) comprise faces that are arranged on the female part (8) and the male part (10), said faces being in abutment against each other when the first unit (3) and the second unit (4) are kept together by means of the locking device (14), said faces being such arranged in the direction of the peripheries of the male part and the female part, respectively, that by a turning of the first unit (3) in relation to the second unit (4) an axially extending force component is provided for causing the sealing elements to leave their mutual engagement; and

that the separator elements (13) and the locking device (14) are arranged such that they are at an axial distance from each other when the first unit (3) and the second unit (4) are kept together by the locking device (14).

2. A connecting piece (1) according to claim 1, **characterized in** that the separator elements (13) comprise the collar (11), the delimiting edge (15) of said collar being a continuously extending delimiting edge, whereby a connecting line between any two points along the delimiting edge (15) in the peripheral direction of the male part (10) is less than 90° in relation to the axial extension of the male part (10) and the female part (8).

3. A connecting piece (1) according to claims 1-2, **characterized in** that the delimiting edge of the collar provides at least two tongues (16), said delimiting edge being congruent with the delimiting edge (17) of the female part.

4. A connecting piece (1) according to any one of the preceding claims, **characterized in** that the delimiting edge of the collar follows the shape of a wave and has a uniform distance between the wave crests (18).

5. A connecting piece (1) according to any one of the preceding claims, **characterized in** that the first sealing elements (9) comprise an annularly extending bead (19) arranged on the inner face of the female part; and that the second sealing elements (12) comprise an annular recess (20) arranged on the outer face of the male part, and which also provide the locking device (14).

6. A connecting piece (1) according to any one of the preceding claims, **characterized in** that the first sealing elements comprise an annular recess (21), the delimiting side faces (22) of which are essentially axially parallel with the centre axis of the female part; and that the second sealing elements (12) comprise an annular flange (23) for providing the delimiting edge (24) of the male part.

7. A connecting piece (1) according to claim 6, **characterized in** that the delimiting side faces (25) of the annular flange of the male part extend taper-

ingly in relation to the central axis of the flange (23) and converge towards the delimiting edge (26) of the flange.

5 8. A connecting piece (1) according to claims 6-7, **characterized in** that the medially arranged side face for the annular recess of the first sealing elements (9) comprise a beveling (29), said beveling facing laterally.

10 9. A connecting piece (1) according to claim 7 or 8, **characterized in** that one face (27) of the annular bead of the female part extends taperingly and converges in a direction towards the annular recess (28).

10. A connecting piece (1) according to any one of the preceding claims, **characterized in** that the first connecting unit comprises a valve (30).

15 11. A connecting piece (1) according to claim 10, **characterized in** that the valve (30) comprises a housing having a displacer means (31) which is displaceable within the housing and perpendicular to the central axis of the first connecting unit, being intended for regulating the passage of liquid in the first connecting unit.

20 12. A connecting piece (1) according to claim 11, **characterized in** that the displacer means comprises stops (32) mounted at each end of the displacer means.

25 13. Use of a connecting piece (1) according to claims 1-12 for establishing connection between a catheter (33) and a urine discharge bag (34).

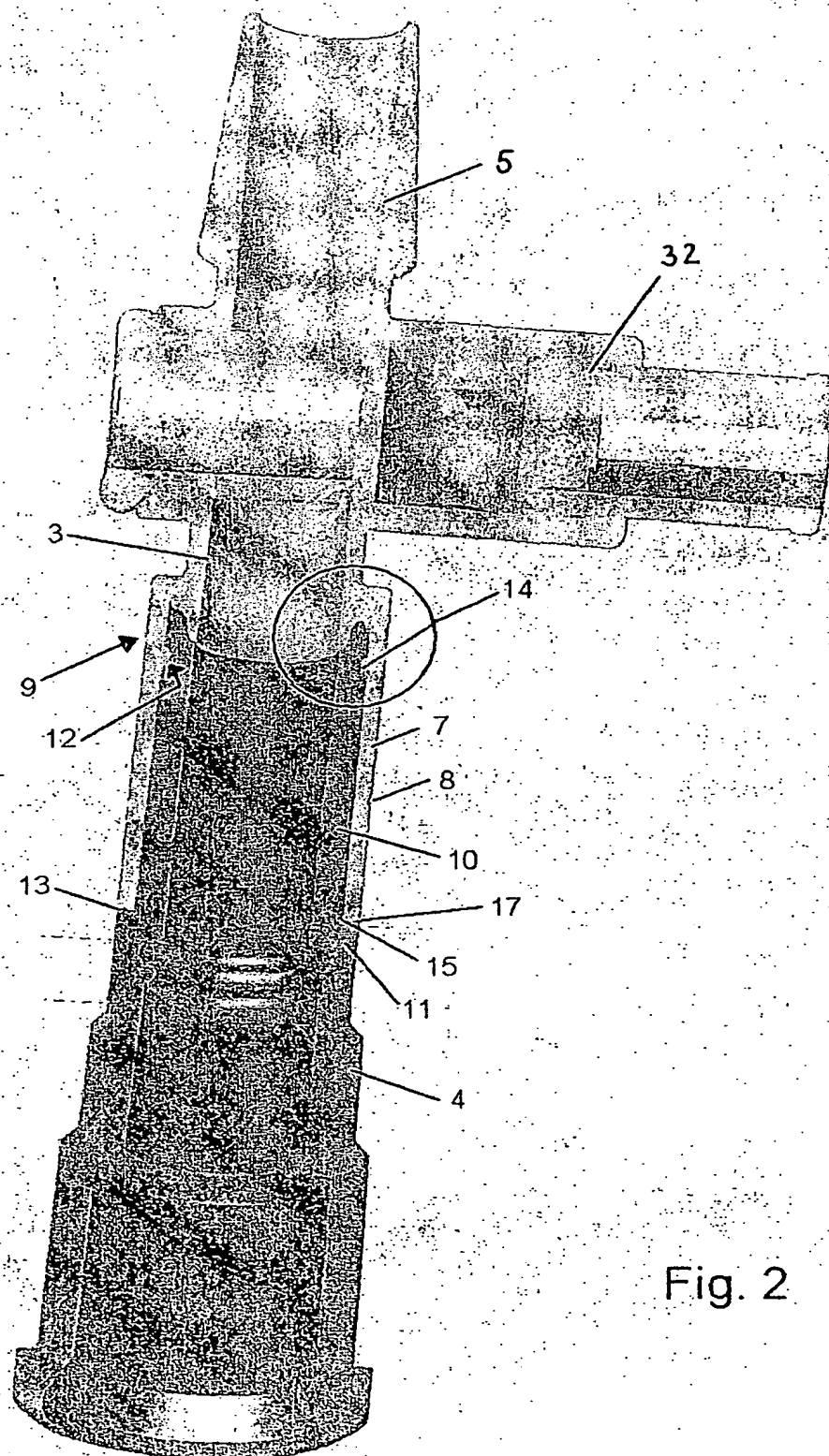


Fig. 2

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